K050848 p1/2

TORNIER

Implants Chirurgicaux

Summary of Safety and Effectiveness information
510(k) – TORNIER Elbow Prosthesis

JUL 1 4 2005

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	***Latitude Elbow Prosthesis***
Common name:	Total Elbow Prosthesis
Classification name:	Elbow joint metal/polymer semi-constrained cemented prosthesis Elbow joint metal/metal or metal/polymer constrained cemented prosthesis

2) Submitter

Tornier S.A.
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier S.A.
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Regulatory affairs & Quality Engineer
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38330 Montbonnot - France
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4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	JDB and JDC

§ 888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis
§ 888.3150 Elbow joint metal/metal or metal/polymer constrained cemented prosthesis

5) Equivalent / Predicate device

Coonrad / Morrey Total Elbow, Zimmer (K973357)
Sorbie - Questor Elbow System, Wright (K955099)
Tornier Elbow Prosthesis, Tornier (K000003, K011567 and K031218)

6) Device description

Total Elbow replacement is used to treat a number of clinical conditions such as severe pain or significant disability in degenerative, rheumatoid or traumatic disease of the elbow joint. It is also used in revision procedures where other treatments or devices have failed and treatment of fractures that are unmanageable using other techniques. The usual goal of such surgery is to restore the elbow joint to its best working

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condition and to reduce or eliminate pain. The *Tornier Elbow Prosthesis* is intended to accomplish these goals. The Tornier Elbow prosthesis is intended for use as a cemented total elbow.

The *Tornier Elbow Prosthesis* is a 3-part system consisting of a humeral, a ulnar and a radial component. The humeral implant is modular and consists in the assembly of various sizes of humeral stem and humeral spool in order to better reproduce the functionality of the natural humerus.
The prosthesis is a non constrained prosthesis and when it is used with the ulnar cup the prosthesis becomes a constrained prosthesis.

The present device submission consists in the addition of two components to the previous cleared devices of the *Tornier Elbow Prosthesis*.
1st addition: ulnar bushing
2nd addition: individual humeral screw
The fundamental scientific technology (intended use, material, manufacturing methods, packaging and sterilization) of the *Tornier elbow Prosthesis* has not changed relative to the predicate device.

7) Materials
Humeral implant components are available in CoCr alloy according to standard ISO 5832-7 or ISO 5832-12 or ISO 5832-4. The ulnar and radial components are made of CoCr alloy according to standard ISO 5832-7 or ISO 5832-12 or ISO 5832-4, and UHMWPE according to standard ISO 5834-2. The humeral screw is made of stainless steel according to ISO 5832-9.

8) Indications
The *Tornier Elbow Prosthesis* is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability following the effects of primary or secondary osteoarthtitis and rheumatoid arthritis; correction of functional deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are unmanageable using other techniques.
The *Tornier Elbow Prosthesis* is intended for cemented use only.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2005

Ms. Mireille Lémery
Regulatory Affairs & Quality Engineer
Tornier S.A.
ZIRST – 161, rue Lavoisier
38330 Montbonnot - France

Re: K050848
Trade/Device Name: Tornier Elbow Prosthesis
Regulation Number: 21 CFR 888.3160, 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer semi-constrained cemented prosthesis, Elbow joint metal/metal or metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDB, JDC
Dated: May 31, 2005
Received: June 02, 2005

Dear Ms. Mireille Lémery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050848

Device Name: *Tornier Elbow Prosthesis*

Indications For Use:

The *Tornier Elbow Prosthesis* is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability following the effects of primary or secondary osteoarthtitis and rheumatoid arthritis; correction of functional deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are unmanageable using other techniques.
The *Tornier Elbow Prosthesis* is intended for cemented use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050848